§112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserts that the terms "blended glass temperature" (claims 3 and 7) and "rated burst pressure" (claims 4, 8, 12, 15, 18 and 21) need clarification.

Claims 3 and 7 have been amended. Support for the amendment is found on page 9 of the specification. Claim 11, which was not rejected, but which used terminology similar to claims 3 and 7, has also been amended to conform the terminology to the other claims.

Applicant traverses the rejection with respect to claims 4, 8, 12, 15, 18 and 21. "Rated burst pressure" is a term of art known and recognized by those of ordinary skill in the art. See the enclosed list of patents found to include the term "rated burst pressure".

As "rated burst pressure" is a known term of art, Applicant respectfully requests withdrawal of the rejection of claims 4, 8, 12, 15, 18 and 21 under 35 U.S.C. §112, second paragraph.

35 U.S.C. §103(a)

Claims 1-21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fugoso et al. (US 5,964,778). The Office Action asserts that Fugoso teaches a blend of polyurethanes (col. 4, line 64) that can be used in making catheter balloons (title), and that it would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ, as the polyurethanes in the blends of Fugoso, polyurethanes having low glass transition temperatures in order to lower the energy required to make the balloons.

Applicant traverses the rejection.

The present invention is directed to specific blends of subgroups of polyurethanes, each subgroup of which has its own glass transition temperature range or its own hardness range (page 9, lines 9-24). By blending polyurethanes from these subgroups, the present inventors have found that specific performance characteristics can be obtained. Furthermore, by employing certain blends, balloons which are compliant,

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semi-compliant or non-compliant can be obtained depending on the type of balloon which is most desirable for the medical procedure being performed.

The blends according to the invention have been found to exhibit surprisingly high rated and mean burst pressure characteristics, low compliance and excellent fatigue resistance, along with excellent folding and performance characteristics, such as track and cross and recross, allowing for construction of dilatation catheter balloons which have the ability to cross multiple lesions. See page 6, lines 19-23.

First of all, Fugoso suggests that preferred balloon materials include PEBA, PET, PE, polyurethane, nylon or blends thereof, but does not teach any specific blends other than to state at column col. 4, lines 55-67 that "[I]it is important to note that PEBA, PET, polyurethane and nylon are thermally incompatible with HDPE." Thus, Fugoso et al. are not specifically describing any blends of polyurethanes. Thus, from the description of Fugoso, it would be just as likely that a blend of polyurethane and PEBA, PET or nylon would be selected as it would be to select a blend of polyurethanes.

Furthermore, there is no teaching or suggestion by Fugoso et al. to select any polymers based on glass transition temperatures, much less to suggest blending more than one polymer having different glass transition temperatures to obtain balloons exhibiting improved performance characteristics

The Office Action argues that it would have been obvious at the time the invention was made to employ, as the polyurethanes in the blends of Fugoso, polyurethanes having low glass transition temperatures in order to lower the energy required to make balloons, and that the selection of polyurethanes having low glass transition temperatures and therefore low production temperature is deemed a matter of engineering choice, depending on the need to lower energy demand in the manufacturing process.

Applicant disagrees with this argument. Polymers including polyurethanes, are available with a vast range of different glass transition temperatures. The Office Action gives no indication as to what the starting point is from where the glass transition temperature is being lowered. Therefore, it is safe to conclude that one would not actually know if the glass transition temperature is being ***raised or lowered***. It is

therefore safe to conclude that not in every instance would the glass transition temperature actually be lower after blending. For example, in the table on page 9 of the above-referenced patent application, a non-compliant balloon may be obtained by blending a polymer having a glass transition temperature of 65° C to 100° C, a glass transition temperature which is actually quite high, with a polymer having a glass transition temperature of 0° C to 10° C. Therefore, the argument that it would have been obvious to employ polyurethanes having low glass transition temperatures to lower the energy required to make balloons cannot stand because in fact, depending on the point from where one is starting, it may in fact be the case that the glass transition temperature is being ***raised.*** The following list, obtained from the website http://www.uscs.edu/~llever/Polymer%20Resources/GlassTrans.htm#glass, shows a list of polymers with approximate glass transition temperatures (T_g).

Table 1

Polymer	T_g (°C)
Polyethylene (LDPE)	-125
Polypropylene (atactic)	-20
Poly(vinyl acetate) (PVAc)	28
Poly(ethyleneterephthalate) (PET)	69
Poly(vinyl alcohol) (PVA)	85
Poly(vinyl chloride) (PVC)	81
Polypropylene (isotactic)	100
Polystyrene	100
Poly(methylmethacrylate) (atactic)	105

As can be seen from the list, adding a polyurethane having a T_g in the range of 65° C to 100° C would not actually lower the T_g, but may in fact raise it.

Applicant submits that the reference is lacking not only the specific teaching or suggestion of blending polyurethanes, but also the teaching or suggestion of selecting polymers based on glass transition temperatures to get improved properties.

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Based on the foregoing arguments, Applicant respectfully requests withdrawal of the rejection of claims 1-23 as being obvious over Fugoso et al.

CONCLUSION

Applicant has addressed each of the issues presented in the Office Action. Claims 1-23 are pending in the application. Applicant respectfully requests reconsideration and an early allowance of the claims as presented.

Please charge the three month extension fee of $930.00 to our Deposit Account No. 22-0350. If any additional fees are required, please charge them to deposit account no. 22-0350.

Respectfully submitted,

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MARKED UP VERSION TO SHOW CHANGES MADE

3. (Amended) The catheter balloon material as recited in Claim 1, wherein said blend has a [blended] glass transition temperature in the range of 22 to 26 degrees C.

7. (Amended) The catheter balloon material as recited in Claim 5, wherein said blend [comprises] has a [blended] glass transition temperature in the range of 26 to 42 degrees C.

11. (Amended) The catheter balloon material as recited in Claim 9, wherein said blend [comprises] has a [blended] glass transition temperature in the range of 43 to 90 degrees C.

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USPTO PATENT FULL-TEXT AND IMAGE DATABASE

Searching 1976 to present...

Results of Search in 1976 to present db for:
SPEC/("rated burst pressure" AND balloon): 21 patents.
Hits 1 through 21 out of 21

Jump To

Refine Search spec/("rated burst pressure" and balloon)

	P.AT. NO.	Title
1	6,495,090	Method of manufacture of semi-compliant catheter balloons
2	6,416,494	Semi-compliant catheter balloons and methods of manufacture thereof
3	6,402,720	Balloon catheter with elongated flexible tip
4	6,383,212	Balloon catheter and stent deploying catheter system
5	6,355,013	Balloon catheter with longitudinal safety stop
6	6,306,073	Apparatus and method for treating a disease process in a luminal structure with a radionuclide and chelating agent
7	6,217,503	Apparatus and method to treat a disease process in a luminal structure
8	6,200,325	Balloon catheter and stent deploying catheter system
9	6,039,755	Radially expandable tubular polytetrafluoroethylene grafts and method of making same
10	6,013,728	Polymer blends for use in making medical devices including catheters and balloons for dilatation catheters
11	5,924,973	Method of treating a disease process in a luminal structure
12	5,849,846	Balloons for medical catheters
13	5,843,027	Balloon sheath
14	5,749,890	Method and system for stent placement in ostial lesions
15	5,747,591	Polymer blends for use in making medical devices including catheters and balloons for dilation catheters
16	5,690,613	Rapid exchange high pressure transition for high pressure catheter with non-compliant balloon
17	5,681,522	Method and apparatus for annealing angioplasty balloons to improve re-wrappability thereof
18	5,669,924	Y-shuttle stent assembly for bifurcating vessels and method of using the same
19	5,643,209	High pressure balloon tip

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20 5,565,523 Polymer blends for use in making medical devices including catheters and balloons for dilatation catheters

21 5,554,120 Polymer blends for use in making medical devices including catheters and balloons for dilatation catheters

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